



**REVISED ORDER AUTHORIZING DISPENSING
AND ADMINISTERING OF THE COVID-19
VACCINE UNDER VIRGINIA CODE 54.1-3408(P)**

Date Issued: May 12, 2021

Purpose: To reduce morbidity and mortality from COVID-19 (SARS-CoV-2) by vaccinating persons who meet the criteria authorized by the Food and Drug Administration Emergency Use Authorization (EUA) and in accordance to the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations. This order is intended to supplement existing authorization under the Public Readiness and Emergency Preparedness (PREP) Act.

This order authorizes pharmacists actively licensed in or outside of Virginia who are in good standing to practice in Virginia per the Virginia Board of Pharmacy to dispense and administer FDA-authorized COVID-19 vaccines. This order also authorizes pharmacy technicians and pharmacy interns who have satisfied the requirements of the PREP Act acting under the supervision of a pharmacist, as defined above, who have enrolled in the CDC COVID-19 vaccination program to administer FDA-authorized COVID-19 vaccines. Eligible providers shall administer the COVID-19 vaccine in accordance with Virginia Code §54.1-3408 (P) as described below.

This order is effective to the earlier of two (2) years from the date of issuance or the expiration of the declaration of emergency, unless otherwise discontinued by the Commissioner. The pharmacy must have an approved CDC provider agreement and must adhere to all policies and procedures included in the agreement, including ensuring proper vaccine storage and handling and cold chain documentation. In addition, the pharmacy must adhere to all CDC-recommended guidelines for maintaining physical distancing and must comply with any applicable federal or state mandates, including executive orders issued by the Governor.

The pharmacy must maintain a copy of the standing order if administering vaccine pursuant to the order.

Please call the Office of the Commissioner at (804) 864-7001 with questions about the standing order.

Eligible Vaccine Recipients*:

Pfizer-BioNTech COVID-19 Vaccine:
Individuals 12 years of age and older requesting COVID-19 vaccination.

Moderna COVID-19 Vaccine:
Individuals 18 years of age and older requesting COVID-19 vaccination.

J&J COVID-19 Vaccine:
Individuals 18 years of age and older requesting COVID-19 vaccination.

** Order is consistent with the FDA EUA. As the EUA is modified, the standing order will be revised.*

Additional Criteria:

- COVID-19 vaccines shall not be administered if there is previous history of completion of a 2-dose COVID-19 vaccination, regardless of brand.



Procedures:

- Screen for any vaccine precautions and contraindications using an appropriate pre-vaccine questionnaire **before** administering the vaccine.
- Provide the vaccine recipient with a copy of the current federal EUA Fact Sheet for Recipients and Caregivers.
- Provide the v-safe information sheet to vaccine recipient/caregiver.
- Obtain informed consent of the patient or parent, guardian, or person standing in loco parentis.
- Educate about where, how, and when to obtain the **second** COVID-19 vaccination.
- Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine.
- Ensure pharmacist accessibility, as defined by the PREP Act, to provide medication supervision of the vaccination site/service, to assess and evaluate individuals who present with precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.
- Review Interim Clinical Considerations for Use of COVID-19 vaccines (<https://www.cdc.gov/vaccines/covid-19/info-by-product/>).

Product Selection/Dose:

Pfizer-BioNTech COVID-19 Vaccine:
Administered intramuscularly as a series of two doses (0.3 mL each), 3 weeks (21 days) apart. Follow VDH clinical guidance for preparation and administration.

Moderna COVID-19 Vaccine:
Administered intramuscularly as a series of two doses (0.5 mL each), 1 month (28 days) apart. Follow VDH clinical guidance for preparation and administration.

J&J COVID-19 Vaccine:
Administered intramuscularly as a single dose (0.5 mL). Follow VDH clinical guidance for preparation and administration.

Contraindications:

Do not administer the Moderna COVID-19 vaccine or Pfizer BioNTech COVID-19 vaccine to anyone with a known history of an immediate or severe allergic reaction (e.g., anaphylaxis) to a prior dose of mRNA COVID-19 vaccine (i.e. Moderna or Pfizer-BioNTech COVID-19 vaccines), polysorbate, or to any component of either mRNA COVID-19 vaccine (including polyethylene glycol [PEG]) listed in the prescribing information.

Do not administer the J&J COVID-19 vaccine to anyone with known history of an immediate or severe reaction to any component of J&J COVID-19 vaccine or to any or to any component of either mRNA COVID-19 vaccine (including polyethylene glycol [PEG]) listed in the prescribing information.

Precautions:

- History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy
- Self-reported moderate to severe acute illness



Directions for Use:

Pfizer-BioNTech COVID-19 Vaccine:

Using aseptic technique, mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride diluent according to manufacturer's instructions. Inject 0.3 mL by intramuscular injection into the deltoid muscle of the arm.

Moderna COVID-19 Vaccine:

Using aseptic technique, withdraw 0.5 mL of the Moderna COVID-19 vaccine from the multi-dose vial and administer by intramuscular injection into the deltoid muscle of the arm.

J&J COVID-19 Vaccine:

Using aseptic technique, withdraw 0.5 mL of the J&J COVID-19 vaccine from the multi-dose vial and administer by intramuscular injection into the deltoid muscle of the arm.

Post-vaccination Observation and Emergency Protocol:

- In accordance with ACIP's General Best Practices Guidance for Immunization, all individuals receiving a vaccine should be observed for at least 15 minutes following vaccination. Persons with a history of anaphylaxis should be observed for 30 minutes.
- Vaccine providers shall be prepared to manage medical emergencies by having a written emergency medical protocol with policies, procedures, and standing orders, as well as appropriate equipment and medications (e.g. epinephrine, diphenhydramine), in places where vaccines are provided according to CDC Clinical Considerations for Managing Anaphylaxis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis>).
- Report any vaccine administration errors (whether or not associated with an adverse event), serious adverse events (irrespective of attribution to vaccination), cases of Multisystem Inflammatory Syndrome in children and adults, or cases of COVID-19 that result in hospitalization or death following administration of the vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) via the VAERS online reporting tool (<https://vaers.hhs.gov/reportevent.html>) or by calling 1-800-822-7967.

Reporting and Follow-Up:

- Record COVID-19 vaccination in the pharmacy record within 24 hours and ensure all required data elements are reported to the Virginia Immunization Information System (VIIS) within 24 hours of vaccine administration.
- Vaccine recipients and/or their parent, guardian, or person standing in loco parentis must be provided with a personal vaccine record indicating the date of vaccination, product name/manufacturer, lot number, name/location of administering pharmacy, and when the recipient needs to return for the second dose of either the Pfizer-BioNTech or the Moderna COVID-19 Vaccine.
- The second dose of the vaccine, if indicated, must be scheduled before the individual leaves the pharmacy.

Prescriber:

DocuSigned by:

M. Norman Oliver, MD

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Virginia Department of Health

Date: May 12, 2021